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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,053	11/03/2003	Anna Gutowska	23-66882	5500

7590            07/27/2004

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EXAMINER
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JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.	GUTOWSKA ET AL.
10/701,053	
Examiner D. L. Jones	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 03 May 2004.  
2a) This action is FINAL.                    2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 59-68 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 59-68 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/12/04.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the preliminary amendment filed 5/3/04 wherein the specification was amended. In addition, the Examiner acknowledges the preliminary amendment filed 11/3/03 wherein the specification was amended; claims 1-58 were canceled; and claims 59-68 were added.

**Note:** Claims 59-68 are pending.

## **APPLICANT'S INVENTION**

2. Applicant's invention is directed to methods of reversibly sterilizing a mammal and a polymeric compound as set forth in independent claims 59, 62, and 64.

## **DOUBLE PATENTING REJECTIONS**

### **Statutory Double Patenting**

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 64-68 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 10-17 of prior U.S. Patent No. 6,660,247. This is a double patenting rejection.

Note: The claims are the same because both are directed to a polymeric compound comprising a polymeric solution. The intended use of the compound is not given patentable weight in a product claim. In addition, it is noted that other characteristics present in the product claim are describing how the polymeric solution undergoes changes during reverse sterilization.

#### **Obviousness-type Double Patenting**

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 59-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-31 of U.S. Patent No. 6,660,247. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are directed to a method of forming a reversible gel by exposing a polymeric solution to at least two environmental stimuli. The claims differ in that the instant invention specifies that the polymeric compound is used in sterilization. It would be obvious to one of ordinary skill in the art to use the polymeric compound for sterilization because claims 22 and 23 of the patented invention disclose that the polymeric solution may be injected into a specific locus in the body or injected into the body to achieve therapeutic embolization.

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## 112 FIRST PARAGRAPH REJECTION

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 59-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising a methacrylamide derivative and a hydrophilic comonomer (wherein the hydrophilic monomer is one that co-polymerizes with methacrylamide and is selected from the group consisting of carboxylic acids, methacrylamide, hydrophilic methacrylamide derivatives, and hydrophilic methacrylic acid esters and the methacrylamide derivative is an N-alkyl substituted methacrylamide selected from the group consisting of N-isopropylmethacrylamide, N,N-diethylmethacrylamide, N-methacryloylpiperidine, N-ethylmethacrylamide, and combinations thereof), does not reasonably provide enablement for all polymeric compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to a method and compound comprising a polymeric compound having a polymeric solution that upon exposure to stimuli becomes a gel.

**(2) State of the prior art**

The references do not indicate all possible polymeric solutions or class of polymeric solutions that are useful with the claimed invention.

**(3) Level of one of ordinary skill in the art**

The level of one of ordinary skill in the art is high. Independent claims 59, 62, and 64 encompass a vast number of possible polymeric compounds. Applicant's specification does not enable the public to make or use such a vast number of possible polymeric compounds.

**(4) Level of predictability in the art**

The art pertaining to the polymeric compounds is highly unpredictable. Determining the various types of compounds or class of compounds in combination with the stimuli necessary to cause a transformation to the gel state requires various experimental procedures and without guidance that is applicable to all polymeric compounds, there would be little predictability in performing the claimed invention. Hence, there is little predictability in performing the claimed invention, absent some guidance.

**(5) Amount of direction and guidance provided by the inventor**

Independent claims 59, 62, and 64 encompass a vast number of polymeric compounds. Applicant's limited guidance does not enable the public to prepare such a numerous amount of compounds. There is no directional guidance for the compounds

or specific stimuli necessary to result in the gel being generated. Hence, there is no enablement for all possible permutations and combinations of polymeric compound-stimuli.

**(6) Existence of working examples**

Independent claims 59, 62, and 64 encompass a vast number of polymeric compounds. Applicant's limited working examples do not enable the public to prepare such a numerous amount of compounds and stimuli combinations. While Applicant's claims encompass a plethora of possible polymeric compounds, the specification provides for compositions comprising a methacrylamide derivative and a hydrophilic comonomer (wherein the hydrophilic monomer is one that co-polymerizes with methacrylamide and is selected from the group consisting of carboxylic acids, methacrylamide, hydrophilic methacrylamide derivatives, and hydrophilic methacrylic acid esters and the methacrylamide derivative is an N-alkyl substituted methacrylamide selected from the group consisting of N-isopropylmethacrylamide, N,N-diethylmethacrylamide, N-methacryloylpyrrolidine, N-ethylmethacrylamide, and combinations thereof).

**(7) Breadth of claims**

The claims are extremely broad due to the vast number of possible polymeric compounds and stimuli known to exist.

**(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure**

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

## **112 SECOND PARAGRAPH REJECTION**

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 59-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because one cannot readily ascertain what is being claimed. Specifically, the claims as written read on various polymeric compounds and combinations thereof. However, one of ordinary skill in the art would not be able to ascertain what is encompassed in the claim as written. Applicant is respectfully requested to clarify the claim in order that one may determine what is being claimed.

## 103 REJECTION

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 64, 65, 67, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goupil et al (US Patent No. 6,652,883).

Goupil et al disclose composition comprising macromers having a backbone comprising 1,2-diol and/or 1,3-diol structures. Possible polymers include polyvinyl alcohol and copolymers of vinyl acetate. The macromers form hydrogels (see entire reference, especially, abstract; column 2, lines 24-33). The composition forms a temporary or reversible mass. Bulking may be achieved by using a fully or partially degradable composition or a composition that degrades in response to conditions such as temperature change and pH (column 2, lines 42-53). The backbone macromer may contain methacrylamide (column 3, lines 51-60). In addition, Goupil et al disclose that solutions of other synthetic polymers such as poly(N-alkylacrylamides) also form hydrogels that exhibit thermoreversible behavior (column 5, lines 42-52). Thus, both Goupil et al disclose polymeric compounds.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a polymeric compound comprising a polymeric solution exposed to stimuli because both Goupil et al and Applicant disclose polymeric

compounds wherein the aqueous polymeric solution becomes a gel having been exposed to environmental stimuli. The transformation of the solution to gel is obvious because Goupil et al disclose that changes such as temperature and pH result in a transformation of the solution.

#### **COMMENTS/NOTES**

13. The lined through documents on the PTO-1449 lack dates of publication and the source (i.e., journals) from which they were obtained. Please supply the information in the next correspondence to the Examiner.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1616

July 26, 2004